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**BAI et al.**(10) **Pub. No.: US 2021/0277146 A1**(43) **Pub. Date: Sep. 9, 2021**(54) **ANTI-PCSK9 MONOCLONAL ANTIBODY**(71) Applicant: **BEIJING DONGFANG BIOTECH CO., LTD.**, Beijing (CN)(72) Inventors: **Yi BAI**, Beijing (CN); **Xiaomin LI**, Beijing (CN); **Wen ZHANG**, Beijing (CN); **Shengmei WEN**, Beijing (CN)(21) Appl. No.: **16/321,472**(22) PCT Filed: **Dec. 29, 2017**(86) PCT No.: **PCT/CN2017/119822**

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(57)

**ABSTRACT**

The application discloses an anti-Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) monoclonal antibody, an amino acid sequence comprising coded antibody variable regions and Complementarity-Determining Regions (CDR), the obtaining method, and application of monoclonal antibody. The anti-PCSK9 monoclonal antibodies are screened from a phage antibody library; affinity maturation is achieved by using a method that the phage antibody library is established by means of chain displacement; After screening the light chain CDR1, 2, 3 Mutant Library of monoclonal antibodies obtained from primary screening; monoclonal antibodies having high affinity are selected; then screening the mutant libraries of heavy chain CDR1, 2, 3 regions; and finally the monoclonal antibodies having high affinity are screened. The PCSK9 antibody obtained by the application has good affinity to PCSK9 and can inhibit the binding of PCSK9 with its ligand and can be used for treating dyslipidemia, cardiovascular and cerebrovascular diseases and thrombotic occlusion diseases.

**Specification includes a Sequence Listing.**